

## REMARKS

### Status of the Claims

Claims 1-9, 11-20 and 23-29 are pending in the application. Claims 1-9, 11-20 and 23-27 are rejected.

Claim 14 has been amended to incorporate the limitations of the base and intervening claims. No change in scope is intended or effected.

### Withdrawal of Rejection under 35 USC 112, second paragraph

Applicant notes, with thanks, the withdrawal of the rejection of claim 23 under 35 USC 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter.

### 35 USC 103(a)—Pinchuk, Ruckenstein, Hossainy, and Reference Polymer Properties

Claims 1-7, 9, 11-20 and 23-27 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk et al., US2002/0107330 (Pinchuk) in view of Ruckenstein et al., WO00/59968 (Ruckenstein) further in view of Hossainy et al., US2001/0014717 (Hossainy), as evidenced by *Reference Polymer Properties* article (RPP). This rejection is respectfully traversed.

For a proper obviousness rejection under 35 U.S.C. 103, the differences between the subject matter sought to be patented and the prior art must be such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. §103. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. MPEP 2141. “[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR International Co. v. Teleflex Inc.*, 550 U.S. \_\_\_, 82 USPQ2d 1385 (2007), quoting *In re Kahn*, 441 F.3d 977, 988, (Fed. Cir. 2006). It should be noted that the prior art reference (or references when combined) must teach or suggest all the claimed features. “When determining whether a claim is obvious, an examiner must make ‘a searching comparison of the claimed invention –

*including all its limitations – with the teaching of the prior art.’ ... Thus, ‘obviousness requires a suggestion of all limitations in a claim.’ ...”* *Ex parte Wada and Murphy*, BPAI Appeal No. 2007-3733, January 14, 2008 (emphasis in original) (citations omitted). In addition, there must be a reasonable expectation of success. See MPEP 2143.02.

Pinchuk discloses an intravascular or intervascular medical device comprising a therapeutic agent-releasing biocompatible block polymer, wherein the polymer is a copolymer that may be linear triblock or branched copolymer, said copolymer comprising elastomeric blocks (specifically, polyolefin blocks) and thermoplastic blocks (specifically, vinyl aromatic blocks or methacrylate blocks), especially poly(methyl methacrylate). Moreover, the copolymer may comprise units that have glass transition temperatures above and below ambient temperature.

As noted by the Examiner, Pinchuk does not disclose graft copolymers. Pinchuk also prefers polyolefin blocks as the elastomeric (rubbery) blocks, and says nothing regarding a rubbery block of rubbery acrylic units such as a poly(alkyl acrylate), poly(haloalkyl acrylate) or poly(cyanoalkyl acrylate) blocks (see claim 13), for example a poly(butyl acrylate) block or a poly(methyl acrylate) block (see claim 14).

The Examiner turns to Ruckenstein to make up for the graft copolymer deficiency in Pinchuk and further turns to Hossainy, urging that Hossainy discloses drug-delivering-coatings for implantable devices such as stents and discloses that the device can be coated with a layer containing an acrylate polymer such as methyl acrylate and a therapeutic agent.

The Examiner argues that (a) it is generally *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose and (b) it would thus have been obvious at the time of the invention to modify the insertable or implantable medical device containing elastomeric and thermoplastic block copolymers as described in Pinchuk by using poly(methyl acrylate) as the elastomeric polymer from Hossainy since it is suitable as a coating for drug releasing implantable devices.

Applicant respectfully disagrees.

First, Hossainy describes copolymers of monomers that include methyl acrylate in the middle of an extended description of polymers that stretches for more than two columns.

Importantly, Hossainy does not teach or suggest that a block of the methyl acrylate units would be suitable as an elastomeric block in a block (or graft) copolymer. This deficiency is not made up for by Pinchuk or Ruckenstein.

Nor does Hossainy teach or suggest a polymeric release region comprising an acrylic graft copolymer that controls the release of therapeutic agent upon administration to a patient as claimed. In this regard, Hossainy teaches that acrylates, including copolymers of methyl acrylate, may be useful as a *primer* layer (see paragraphs [0031] through [0036]), but not as a layer for controlling release. This deficiency is not made up for by Pinchuk or Ruckenstein.

Because Hossainy, Pinchuk and Ruckenstein neither teach nor suggest that that acrylates, including copolymers of methyl acrylate, can be used in block copolymers and because Hossainy, Pinchuk and Ruckenstein neither teach nor suggest that that acrylates, including copolymers of methyl acrylate, can be used in a layer for controlling release, it is not *prima facie* obvious to employ such materials in the block copolymer of Pinchuk, much less so in a graft copolymer like that claimed. In this regard, Pinchuk teaches polyolefins for use as such blocks, which are remote from polyacrylates such as poly(methyl acrylate).

The Examiner also argues that, at the time of the invention, it would have been obvious to a person of ordinary skill in the art to create an insertable or implantable medical device (e.g., stent) containing elastomeric and thermoplastic block copolymers as described in Pinchuk while grafting the copolymers of Pinchuk as described in Ruckenstein. The Examiner also alleges that the motivation for grafting the copolymers would have been to control not only the properties of the surface, but also the molecular parameters, architecture, and composition of the polymer as these are disclosed as being advantageous over other types of polymers as explained in Ruckenstein.

In this regard, it is noted that Ruckenstein actually states the following (emphasis added): “The direct synthesis of well-defined graft copolymers *with functional groups* can control not only the properties of the surface, but also the molecular parameters, architecture, and composition of the polymer.” The copolymer of Pinchuk, on the other does not contain functional monomers as described in Ruckenstein. See page 15, lines 19-23.

It is further noted that Hossainy, Pinchuk and Ruckenstein do not teach that graft architecture can be substituted for block copolymer architecture. In fact, Ruckenstein teaches that “it is more difficult to prepare graft copolymers than block copolymers” (page 2, lines 23-24).

For at least the preceding reasons, it is respectfully submitted that the present claims are patentable over Pinchuk, Ruckenstein, Hossainy, and Reference Polymer Properties.

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Examiner: Chris E. Simmons  
Group Art Unit: 1612

**35 USC 103(a)—Pinchuk, Ruckenstein, Hossainy and Williams**

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pinchuk, Ruckenstein and Hossainy as evidenced by *Reference Polymer Properties*, and taken in view of Williams, U.S. 6,514,515 (Williams). Applicant respectfully traverses this rejection.

The present claims are patentable over Pinchuk, Ruckenstein, Hossainy, and Reference Polymer Properties for the reasons set forth above. Williams, which is cited for its teachings including elongation at break, does not make up for these deficiencies.

Consequently, it is respectfully submitted that the present claims are patentable over Pinchuk, Ruckenstein, Hossainy, Reference Polymer Properties and Williams.

**Conclusion**

Should the Examiner be of the view that an interview would expedite consideration of the application, request is made that the Examiner telephone the Applicants' attorney at (703) 433-0510 in order to resolve any outstanding issues.

Respectfully submitted,

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